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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,218	07/08/2003	Yechiel Gotfried	03398/LH	9774
1933	7590	11/01/2007	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC			ARAJ, MICHAEL J	
220 Fifth Avenue			ART UNIT	PAPER NUMBER
16TH Floor			3733	
NEW YORK, NY 10001-7708			MAIL DATE	
			11/01/2007	
			DELIVERY MODE	
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/616,218	GOTFRIED, YECHIEL
Examiner	Art Unit	
Michael J. Araj	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 October 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-10,26,27,83-95,97-99,103-133 and 137-139 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-10,26,27,83-95,97-99,103-133 and 137-139 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The final action mailed on June 14, 2007 has been withdrawn due to the following non-final action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 86-88, 97-99, 103, 105, 106, 110-120, 122,123 and 137-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent No. 5,454,813) in view of Viscount et al. (U.S. Patent No. 7,147,399).

Lawes discloses an intramedullary nail comprising a proximal head that defines at least one hole therethrough, a sleeve comprising a locking mechanism that is adapted to engage the hole when the sleeve is inserted in the hole and a screw where the sleeve is adapted to slidably receive the screw. The proximal head is shaped so as to define a female coupling element, comprising a notch (13a), located on a surface of the hole and where the locking mechanism comprises a depressible male coupling element, comprising a tab (13). The male coupling element is adapted to engage the female coupling element when the sleeve is inserted in the hole to a fixed depth and then rotated until the male coupling element engages the female coupling element. The locking mechanism of each of the at least one sleeve being integral with the at least one sleeve and structured and arranged to cooperate with the position of the nail around the

respective one of the at least one hole to prevent rotational and longitudinal movement between the sleeve and the nail when the sleeve is inserted in the respective hole in the nail. The notches prevent the rotation of the sleeve and the shoulder (16) prevents further longitudinal movement. Lawes also discloses one connecting element, fixed to the distal end of the locating device (32), and a location-indicating element, fixed to a proximal end of the locating device. The apparatus also as an elongated bendable element (7) comprises a sharp tip that is inserted into the hole, through the channel and proximal end of the proximal portion as well as through the bone so as to indicate a location on the external surface of the bone. The sharp tip comprises of a screw thread and/or drill bit.

Lawes discloses the claimed invention except for a locking element with a female coupling element and a depressible male coupling element that is configured to engage the female coupling element so as to prevent the rotational and longitudinal movement between the sleeve and the nail. Viscount et al. discloses the use of a coupling device with an attachment means that locks two respective pieces together preventing longitudinal and rotational movement. They disclose a male coupling element (21) that locks into place with a female coupling element (6). It would have been obvious to one skilled in the art at the time the invention was made to have created the device of Lawes with a snap-fit type locking mechanism in view of Viscount et al., in order to have a device that will be secured well upon placement in the body and avoid the risk of other problems that can arise with movable pieces.

Claims 7, 26, 27 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bramlet et al. (U.S. Patent No. 6,648,889) in view of Viscount et al. (U.S. Patent No. 7,147,399).

Bramlet et al. disclose an intramedullary nail comprising a proximal head that defines at least one hole therethrough, a sleeve comprising a locking mechanism that is adapted to engage the hole when the sleeve is inserted in the hole and a screw where the sleeve is adapted to slidably receive the screw. The head has a distal portion and a proximal portion where the proximal portion has a diameter less than or equal to about 80% of the distal diameter. (see Figure 1 below) The distal portion defines at least one hole therethrough and comprising a sleeve (3), which comprises a locking mechanism (2). This locking mechanism prevents longitudinal and rotational movement of the sleeve with respect to the nail. Also disclosed is that the intramedullary nail is adapted to be implanted in the bone, such that no portion of the nail extends to an external surface of the bone. It also can be interpreted that the proximal head has a visually discrete distal portion and proximal portion. (See Figure 25) There is also a visual discreteness between the proximal and distal portions with respect to the angled hole for the sleeve. There is a sudden narrowing between the proximal and distal portions (as seen below).

Bramlet et al. disclose the claimed invention except for a locking element with a female coupling element and a depressible male coupling element that is configured to engage the female coupling element so as to prevent the rotational and longitudinal movement between the sleeve and the nail. Viscount et al. discloses the use of a

coupling device with an attachment means that locks two respective pieces together preventing longitudinal and rotational movement. They disclose a male coupling element (21) that locks into place with a female coupling element (6). It would have been obvious to one skilled in the art at the time the invention was made to have created the device of Bramlet et al. with a snap-fit type locking mechanism in view of Viscount et al., in order to have a device that will be secured well upon placement in the body and avoid the risk of other problems that can arise with movable pieces.

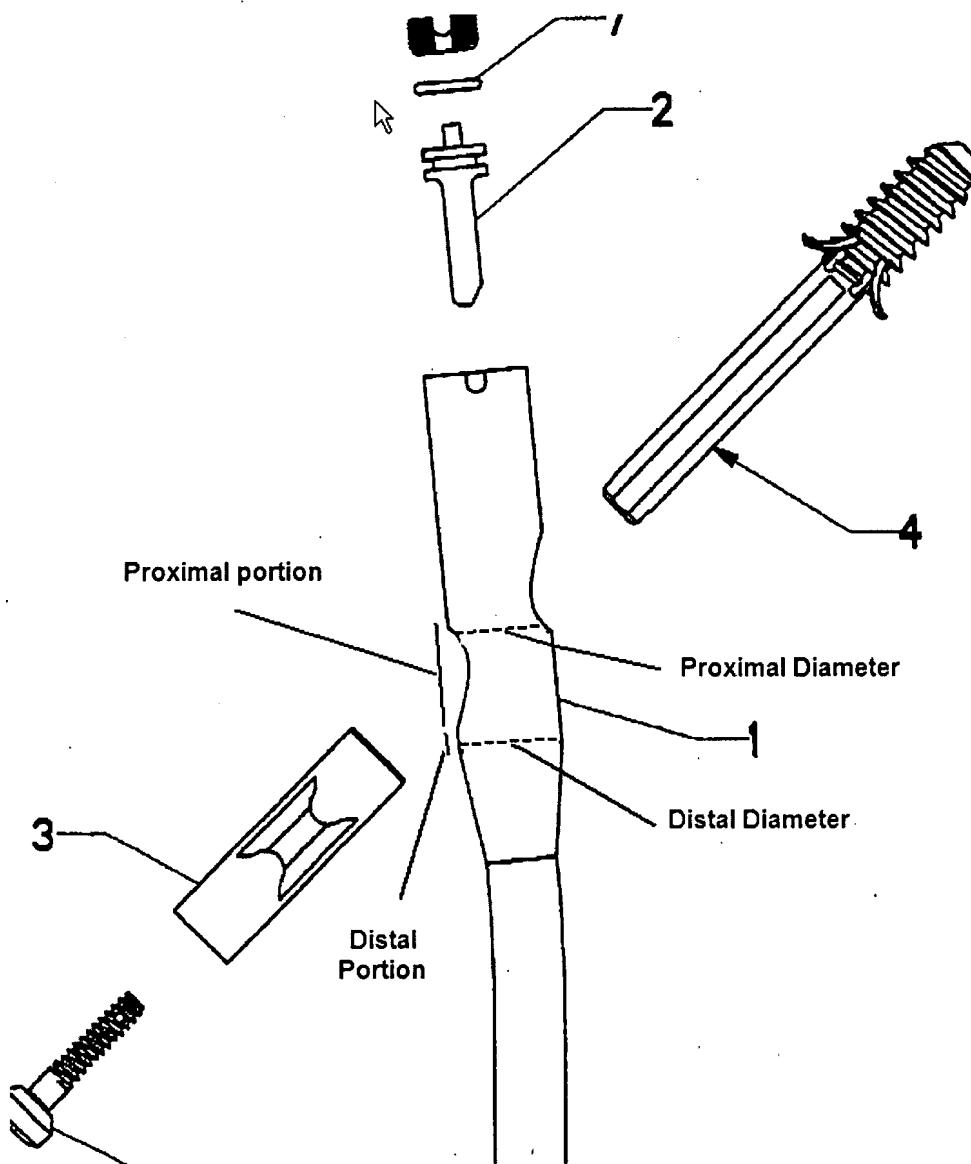


Figure 1 ('889)

Claims 8-10, 90-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bramlet et al. (U.S. Patent No. 6,648,889) in view of Viscount et al. (U.S. Patent No. 7,147,399).

The combination of Bramlet et al. and Viscount et al. disclose the claimed invention except for the ranges of diameter and length in claims 8-10 and 94. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the diameters and lengths as set forth in these claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Bramlet et al. and Viscount et al. disclose the claimed invention except for making the proximal portion of the head removable from the distal portion of the head as in claim 90. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make these two portion separable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

With respect to claims 91-93, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Bramlet in view of Viscount et al. having a plurality of angled holes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 83-85, 107-109, 124-130, 132-136 and 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent No. 5,454,813) in view of Viscount et al. (U.S. Patent No. 7,147,399).

The combination of Lawes and Viscount et al. disclose the claimed invention except for having a plurality of holes with respect to claims 83-85,107-109, 124-130 and 132-136. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Lawes having a plurality of angled holes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Allowable Subject Matter

Upon further search and consideration, the objected material that was considered to be allowable in the action mailed on June 14, 2007 has been withdrawn.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

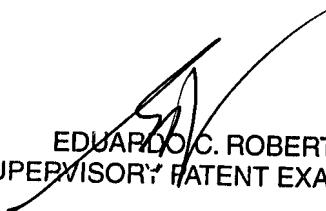
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MJA


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER